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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,316	TENG ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 8/29/2007.

The amendment filed 8/29/2007 is acknowledged and has been entered.

Claims 30-55 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 30-55 are examined herein.

Specification

The amendment filed 5/25/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the new text added to paragraph [0124]. It is noted that applicants have argued that this new material can be added because the specification has incorporated by reference the source for the new text. It is acknowledged that Applicants have incorporated by reference the source for the new text. However, the instant insertion of new text, which is essential material, into the specification by reference to a publication is improper because **the amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re**

Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Applicant is required to cancel the new matter in the reply to this Office Action or to resubmit the amendment with the appropriate affidavit or declaration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was

filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

In this case, claims 48 and 54 include the limitation that the capsule is a single compartment capsule (Emphasis added). Applicants have pointed to amended paragraph 0124 of the specification as support for the limitation "single compartment capsule". However, as indicated above, the amendment to paragraph 0124 has not been entered. As such, the version of paragraph 0124 prior to the non-entered amendment was closely reviewed by the Examiner, however, neither explicit, implicit nor inherent support for a "single compartment capsule" was found in this paragraph 0124, or anywhere else in the specification, as previously indicated.

Briefly, instant paragraph 0124 does not contemplate using the species which is a single compartment capsule. Since the disclosure of a broad genus does not anticipate every species which it encompasses, the disclosure of paragraph 0124 does provide proper support for a single compartment capsule.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 30-36, 38-55 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,877,309 (McKay et al.)

McKay teaches a method which comprises administering to a human a composition comprising a drug that is an antisense oligonucleotide (e.g., column 6, lines 29-65); wherein the antisense oligonucleotide is comprised in a formulation for oral delivery which can comprise a polyacrylic polymer, such as capric acid and polyacrylates (e.g., see: col. 20, lines 52-54; col.22, lines 4-19; col. 23, lines 24-40; col. 25, lines 1-7; and col. 28, lines 3-4). McKay teaches that the therapeutic formulation can be comprised in a capsule or tablet, which as described by McKay would be a single compartment capsule (e.g., see column 22, lines 49-60). It is noted that a tablet, as described in McKay would necessarily release the populations of particles it contains concurrently. Furthermore, McKay does not indicate that the capsules or tablets can be multicompartment capsules. Additionally, McKay teaches that the antisense drug composition can comprise hydroxypropylmethylcellulose and polyacrylates (e.g., see col. 23, lines 29-40). McKay also teaches that the formulation which comprises the second population of carriers can

further comprise an enteric coating (e.g., see column 20,line 43 through column 21, line 4; also see column 23, lines 24-48). McKay also teaches that in general the pharmaceutical compositions can be prepared by uniformly and intimately bringing into association the active ingredient(s) with liquid excipients or finely divided solid excipients or both, and then, if necessary, shaping the product (see column 21, lines 40-50).

Therefore, McKay teaches a method comprising administering to a subject a composition comprising all of structural elements of instant claims. Therefore, the method taught by McKay, absent evidence to the contrary, would necessarily have the same result as the instant claimed method.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 30, 33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,877,309 (McKay et al.), further in view of US Patent 5,514,788 (Bennett et al.).

It is noted that McKay teaches a method for enhancing the intestinal absorption of an antisense drug in an animal, comprising administering to the animal a formulation comprising: (a) a first population of carrier particles comprising an drug-bioadhesive component, wherein the drug is an antisense oligonucleotide; and (b) a second population of carrier particles comprising a penetration enhancer, as indicated above.

McKay does not teach that the oligonucleotide comprises SEQ ID NO: 1 (claim 37).

However, Bennett teaches an antisense oligonucleotide that exactly matches SEQ ID NO: 1 of the instant claims (see SEQ ID NO: 22 in column 35 of Bennett) wherein the antisense oligonucleotide can be used administered to an animal for a method of treatment (e.g., see abstract).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of McKay and Bennet to make a method comprising administering to an animal a composition comprising (a) a first population of carrier particles comprising an drug-bioadhesive component, wherein the drug is an antisense oligonucleotide comprising the antisense oligonucleotide taught by Bennet; and (b) a second population of carrier particles comprising a penetration enhancer, with a reasonable expectation of success.

The motivation to make the modification is provide in part by both McKay and Bennett. Specifically, McKay teaches a method for administering a therapeutic antisense oligonucleotide to an animal and Bennett teaches a specific therapeutic antisense oligonucleotide comprising SEQ ID NO: 1.

Response to Arguments

6. Applicant's arguments filed 5/25/2007 have been fully considered but they are not persuasive.

Applicants assert that the amendment to the specification, paragraph [0124] is not new matter as the source of the text was incorporated by reference. This is not persuasive as Applicant has not filed the appropriate Affidavit or Declaration as indicated above.

With respect to the New Matter rejection as it was previously applied it is noted that the amendment to the independent claims obviates the rejection as the independent claims no longer include the limitation "single compartment capsule". However, Applicants have added new claims 48 and 54 which are drawn to a "single compartment capsule". Therefore, the new claims are now rejected under 35 USC 112, 1st paragraph (New Matter) essentially for the same reasons and the new grounds of rejection is necessitated by the amendment which adds the new claims. With respect to the arguments as they apply to the new grounds of rejection, it is noted that the amendment to the specification has not been entered for the reasons indicated herein, therefore paragraph 0124 does not provide adequate support for the claim limitation. It is noted that submitting a proper Affidavit or Declaration as indicated above would allow for entry of the amendment and would obviate the instant rejection.

With respect to the rejection of claims under 35 USC 102 and 103, Applicants argue that McKay does not disclose the use of two populations of carrier particles as claimed in the instant application. It is also acknowledged that McKay was previously applied in a rejection and then the rejection was withdrawn in view of the amendment to the claims and in view of applicants' arguments. Applicants have resubmitted essentially the same arguments.

In response, upon further consideration of the McKay reference, it was determined that although McKay does not appear to explicitly disclose a formulation comprising a "first population of carrier particles comprising a drug-bioadhesive component" and "a second population of carrier particles comprising a penetration enhancer" as currently claimed, McKay does in fact teach formulations for oral delivery where the formulation comprises a penetration enhancer, such as fatty acids, bile salts, etc. (e.g., see column 22). McKay also teaches that the composition can comprise at least one element that is a "penetration enhancer", as defined by the instant specification (e.g., see claim 35 which indicates some specific "penetration enhancers"), such as polyacrylic polymers (e.g., see column 22). Therefore, McKay does teach a composition which comprises a first population of carrier particles comprising a drug-bioadhesive component and a second population of carrier particles comprising a penetration enhancer. Therefore, McKay teaches a composition which includes all of the structural elements of the claims rejection under 35 USC 102. Therefore, Applicants arguments are not persuasive.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635